REMARKS

Upon entry of this Amendment, claims 1-25, 29-31, and 39-41 are canceled, claims 26, 27, 34, 36, and 37 are amended, claims 28, 32, 33, 35, 38, and 42-47 are previously presented, and claims 48-50 are added. No new matter has been added by these claims or amendments. Upon entry of this Amendment, claims 26-28, 32-38, and 42-50 are pending. The amendments to the claims have been done to make explicit what was implicit in the specification. Support for these claims can be found through out the Application as filed, particularly on page 6, line 25 through page 7, line 22; page 7, lines 6-22; page 7, line 33 through page 8, line 1; page 8, lines 25-28; and page 12, lines 24-26. Applicants respectfully request reconsideration and withdrawal of the rejections in view of the amendments and following remarks.

I. Claim Rejections.

A. The Rejections Under 35 USC §101/112 May Be Properly Withdrawn

Claims 26, 28, 32, 33, 36, 38, 42-47 are rejected under 35 USC §112, second paragraph, as failing to set forth the subject matter which Applicants regard as their invention. Applicants submit that, with the amendments to the claims, this rejection is rendered moot. Applicants respectfully submit that this rejection under 35 USC §112, second paragraph, may be properly withdrawn. Applicants respectfully request withdrawal of this rejection.

Claims 34 and 35 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Applicants submit that, with the amendments to the claims, this rejection is rendered moot, and request that this rejection under 35 USC §112, second paragraph, be withdrawn.

Claims 34 and 35 are also rejected under 35 USC §101 as the claims are directed to neither a "process" nor a "composition," but rather embraces or overlaps two different statutory classes of invention set forth in 35 USC §101. Applicants submit that, with the amendments to the claims, this rejection is rendered moot, and request that this rejection under 35 USC §101 be withdrawn.

The Examiner stated that there is insufficient antecedent basis for the limitation of "biologically active composition" in claim 34. Applicants submit that, with the amendments to the claims, this issue is rendered moot. Applicants respectfully request this issue be withdrawn.

B. The Rejection Under 35 USC §102(b)/103(a) May Be Properly Withdrawn

Claims 26-28 and 32-34 are rejected under 35 USC §102(b) as anticipated by or, in the alternative, under 35 USC §103(a) as obvious over, Carr et al. (US Pat. 5,227,167). Applicants respectfully traverse this rejection.

A patent is invalid for anticipation under 35 USC §102(b) if a single prior art reference discloses each and every limitation of the invention as set forth in the claims (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. Applicants submit that these criteria are not met in the Examiner's rejection.

As stated in the MPEP (§2141), to support an obviousness rejection (35 USC §103(a)), four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including

parts that teach away from Applicant's invention. Applicants respectfully submit that these criteria are not met.

Nnone of the references cited by the Examiner suggest Applicant's invention. In addition, Applicant respectfully submits that merely because the references can be combined, does not render the combination obvious. The prior art must suggest the desirability of making the combination. *In re Fritch* (CAFC 1992) 972 F2d 1260, 23 PQ2d 1780. Before one determines that the prior art teaches one of ordinary skill in the art to make the changes necessary for the present invention, one must first determine that the prior art suggests that the references be combined. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* (CAFC 1989), 139 F3d 877, 45 PQ2d 1977. However, there is no indication in any of the references that would suggest they be combined, and thus there can be no reasonable expectation that such a combination would be successful. Only hindsight would allow the Examiner to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process.

The standard for obviousness is not combining what one can find in the prior art. It is inappropriate to use applicant's disclosure to assemble an argument. As discussed in *In re Papesch* (315 F.2d 318, 391, 137 USPQ 43, 51 CCPA 1963), "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing... There is no basis in the law for ignoring any property in making such a comparison" (based on the similarity of a compound's formula to the formula of another compound). Thus, it is inappropriate to ignore the properties that the Inventors of the current invention discovered.

Claims 26-28, 32-34, as amended by this paper, focus on Applicants' invention which comprises an implant composition comprising an immediate-release first delivery vehicle selected from the group consisting of solid compressed tablets and solid compressed pellets; and a sustained-release second delivery vehicle selected from the group consisting of solid compressed tablets and solid compressed pellets.

As the Examiner states when describing the sustained release component of the Carr invention, "It is taught that the second beneficial agent formulation may be a liquid, semi-solid or thermoresponsive such as set forth in US Pat. 4,772,474, the disclosure of which is incorporated by reference (Column 8, lines 39-51)." The second beneficial agent formulation is prepared with Multiwax™ which is heated, poured into a cup, and allowed to cool (Column 12, lines 42-51). Thus, Carr's sustained release component, the second beneficial agent formulation, is **not** in the form of a solid, neither a solid compressed tablet nor a solid compressed pellet, as are the sustained release second delivery vehicles of Applicants' invention. Nor does Carr suggest that a solid could be used. Applicants' invention is neither anticipated nor made obvious by Carr because of the different form of the second component described by Carr. Applicants respectfully request withdrawal of this rejection.

Claims 26-28, 32-38, and 42-47 are rejected under 35 USC 103(a) as being unpatentable over Carr et al. (US Pat. 5,227,167) in view of Babcock et al. (US Pat. 3,417,182), and Montgomery et al., and Grimm (US Pat. 5,522,797). Applicants respectfully traverse this rejection. As stated above, Carr's sustained release component, the second beneficial agent formulation, is **not** in the form of a solid compressed tablet or a solid compressed pellet, as are the sustained release second delivery vehicles of Applicants' invention. Applicants' invention is not made obvious by Carr. Babcock does not discuss an immediate and sustained release formulation of a solid compressed tablet or a solid compressed pellet, as does the instant invention. In the Montgomery reference, the melengestrol acetate is fed to the heifers daily and is not administered as an immediate and sustained release formulation of a solid compressed tablet or a solid compressed pellet, as does the instant invention. The Grimm reference discusses an implanter apparatus but does not discuss melengestrol acetate in an immediate and sustained release formulation of a solid compressed tablet or a solid compressed pellet, as does the instant invention. As stated above, the standard for obviousness is not combining what one can find in the prior art. To support an obviousness rejection, the prior art must suggest the desirability of making the combination of the

references. However, there is no indication in any of the cited references that would suggest that the references be combined. Only hindsight would allow the Examiner to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process. In none of the references cited by the Examiner under the 35 USC 103(a) rejection, either alone or in combination, is there a teaching of using a solid form for a second release component. Applicants respectfully request withdrawal of this rejection.

Claims 26-28, 32-38, and 42-47 are rejected under 35 USC 103(a) as being unpatentable over Lewis (US Pat. 5,288,496) in view of Herbert et al. (US Pat. 5,654,008) and Okada et al. (US Pat. 4,652,441) for the reasons of record set forth in the prior Office Actions in further view of Babcock et al. (US Pat. 3,417,182) and Montgomery et al. and the further reasons below. Examiner states, "Applicant references methods of forming granules or pellets which are disclosed in the Specification. However, the claims do not set forth said methods of preparation and do not set forth minimum size for tablets, granules, or pellets or indicate that the same do not include microparticles. In response to the applicant's argument that the references fail to show certain features of the applicant's invention, it is noted that the features upon which applicant relies (i.e., the process in which the pellets, granules or tablets are prepared) are not recited in the rejected claim(s)." Applicants maintain as applicable the arguments set forth in prior responses regarding the fact that there is no suggestion in the references of the desirability to combine the references, with the addition of the remarks in paragraphs 3-5 of Section I (B) above. In addition, Applicants have amended the claims to reflect the fact that a subject matter of their invention is an implant composition in the form of immediate and sustained release solid compressed tablets or solid compressed pellets. Further, claims 48-50 have been added which provide more detail concerning the preparation of these solid compressed tablets and solid compressed pellets. Applicants submit that, with the amendments to the claims, this rejection is rendered moot. Applicants respectfully request withdrawal of this rejection.

The Examiner states that Applicants present no evidence that Herbert et al. does not have an immediate release. Applicants maintain the arguments set forth in prior responses as applicable, and the same is incorporated herein. The data presented in figure 11 of Herbert are quite variable, but the composition probably does not have release rates for each of the peaks. A smooth curve drawn through the data would show an initial peak for approximately the first 20 days followed by substantial decrease in serum levels. This shows ordinary release over a long time period. Applicants respectfully request withdrawal of this rejection.

Claims 26, 32, 33, 36, and 42-47 are rejected under 35 USC 103(a) as being unpatentable over Rickey et al. (US Pat. 5,792,477) for the reasons of record set forth in the prior Office Actions in further view of Babcock et al. and Montgomery et al. and the further reasons below. Applicants maintain as applicable the arguments set forth in prior responses regarding this rejection. The Rickey reference relates to " microparticles having a reduced level of residual solvent(s) and to a method for the preparation of such microparticles (col. 1, lines 12-14) while Applicant's invention pertains to solid compressed tablets or solid compressed pellets as the composition. The Rickey reference mentions melengestrol as a suitable active agent (col. 13, line 25) but this is different than melengestrol acetate as specified in Applicant's claims. In addition, Applicants have amended the claims to reflect the fact that a subject matter of their invention is an implant composition in the form of immediate and sustained release solid compressed tablets or solid compressed pellets. Further, claims 48-50 have been added which provide more detail concerning the preparation of these solid compressed tablets and solid compressed pellets. Applicants submit that, with the amendments to the claims, this rejection is rendered moot. Applicants respectfully request withdrawal of this rejection.

The compositions of Lewis, Herbert, Okada, and Rickey are specifically directed towards microparticles and microcapsules. According to the above references, the preparation of microparticles involves the mixing of a first phase and a second phase with a quenching liquid. The liquid preparations

are very different from solid preparations. The methods for preparing microparticles in the above art, are in no way comparable to the methods Applicants disclose for the preparation of solid compressed tablets and solid compressed tablets of the instant invention (see page 9 lines 19-22, page 14 lines 5-7, and claims 48 and 49).The tablets and pellets of Applicants' invention are prepared by compression. There is no such compression step in the preparation of the above microparticles and microcapsules.

II. Conclusions.

In view of the amendments and remarks made herein, Applicant respectfully submits that claims 26-28, 32-38, and 42-50 are in condition for allowance and respectfully requests expedited notification of same.

Respectfully submitted,

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